AMENDMENTS TO THE CLAIMS

1. (Previously Presented) A process for making a polymeric product having a gradual variation in modulus through at least a portion of the product, comprising the steps of:

(a) reacting at least one of a multifunctional isocyanate, a polyol and a chain extender, wherein at least two reagents selected from the isocyanate, the polyol, the chain extender, any mixture thereof and any pre-polymer formed therefrom, are intensively mixed to form a first polyurethane having a predetermined stoichiometry and thermal history;

(b) reacting at least one of a multifunctional isocyanate, a polyol and a chain extender, wherein at least two reagents selected from the isocyanate, the polyol, the chain extender, any mixture thereof and any pre-polymer formed therefrom, are intensively mixed to form a second polyurethane having a predetermined stoichiometry and thermal history which is different to the stoichiometry and thermal history of the first polyurethane; and

(c) injecting the first and second polyurethanes into a mould defining the polymeric product before the polymerization reactions associated with the production of the first and second polyurethanes are complete so that polymerization reactions between the first and second polyurethanes occur in the mould.

2. (Original) A process according to claim 1, comprising the step of injecting the first and second polyurethanes into the mould simultaneously.

3. (Original) A process according to claim 2, comprising the step of altering the relative rate of injection of the first polyurethane into the mould relative to the rate of injection of the second polyurethane into the mould.

4. (Original) A process according to claim 1, including the step of mixing the first and second polyurethanes prior to injection into the mould via a common injection port.

5. (Original) A process according to claim 4, including the step of altering the length of the common injection port to control the degree of mixing of the first and second polyurethanes prior to injection into the mould.

6. (Previously Presented) A process according to claim 1, including the step of controlling the relative amounts of the first and second polyurethanes injected into the mould.

7. (Original) A process according to claim 6, including the step of injecting the same amount of the first and second polyurethanes in to the mould.

8. (Previously Presented) A process according to claim 1, wherein the method includes the step of forming the first and second polyurethanes simultaneously in a separate apparatus.

9. (Previously Presented) A process according to claim 1, wherein the method includes the step of forming the first and second polyurethanes using the same apparatus, the method comprising the steps of forming the first polyurethane and subsequently perturbing the relative amounts of the reagents to form the second polyurethane.

10. (Original) A process according to claim 9, including the step of passing the first polyurethane into an intermediate vessel before formation of the second polyurethane.

11. (Original) A process according to claim 10, wherein the method includes the step of passing the second polyurethane into an intermediate vessel.

12. (Previously Presented) A process according to claim 11, including the step of simultaneously injecting the first and second polyurethanes into the mould from said intermediate vessels.

13. (Previously Presented) A process according to claim 12, including the step of injecting the first and second polyurethanes into the mould at different injection rates.

14. (Previously Presented) A process according to claim 13, wherein the method includes the step of controlling the temperature of at least one of the intermediate vessels to impart at least one of a different stoichiometry and thermal history to the first and second polyurethanes contained therein.

15. (Previously Presented) A process for making a polymeric product having a gradual variation in modulus through at least a portion of the product comprising the steps of:

(a) reacting at least one of a multifunctional isocyanate, a polyol and a chain extender, wherein at least two reagents selected from the isocyanate, the polyol, the chain extender, any mixture thereof and any pre-polymer formed therefrom, are intensively mixed to form a polyurethane having a predetermined stoichiometry and thermal history;

(b) continuously perturbing the relative amounts of said at least two reagents during the course of the reaction to continuously vary the modulus of the polyurethane so formed; and

(c) injecting the polyurethane into a mould defining the polymeric product before the polymerization reactions associated with the production of the polyurethane is complete so that polymerization continues in the mould.

16. (Previously Presented) A process according to claim 15, wherein the polyurethane is passed through an extruder to be reactively extruded therein.

17. (Original) A process according to claim 16, wherein the polyurethane undergoes thermal profiling during the reactive extrusion step.

18. (Currently Amended) An artificial spinal disc comprising a ~~solid~~ body of polymeric material that at least a pre-determined portion of which exhibits a gradual variation in Young's modulus.

19. (Currently Amended) An artificial spinal disc according to claim 18, wherein the Young's modulus varies substantially linearly through said portion.

20. (Previously Presented) An artificial spinal disc according to claim 18, comprising a nucleus surrounded by an annulus region, said portion being located in a region between the nucleus and annulus regions.

21. (Previously Presented) An artificial spinal disc according to claim 18, including a pair of integral polymeric end plates configured such that there are no interfacial bonds between the end-plates and a remainder of the spinal disc.

22. (Previously Presented) An artificial spinal disc according to claim 18, manufactured by:

(a) reacting at least one of a multifunctional isocyanate, a polyol and a chain extender, wherein at least two reagents selected from the isocyanate, the polyol, the chain extender, any mixture thereof and any pre-polymer formed therefrom, are intensively mixed to form a first polyurethane having a predetermined stoichiometry and thermal history;

(b) reacting at least one of a multifunctional isocyanate, a polyol and a chain extender, wherein at least two reagents selected from the isocyanate, the polyol, the chain extender, any mixture thereof and any pre-polymer formed therefrom, are intensively mixed to form a second polyurethane having a predetermined stoichiometry and thermal history which is different to the stoichiometry and thermal history of the first polyurethane; and

(c) injecting the first and second polyurethanes into a mould defining the polymeric product before the polymerization reactions associated with the production of the first and second polyurethanes are complete so that polymerization reactions between the first and second polyurethanes occur in the mould.

23. (Previously Presented) A surgical implant manufactured according to a process including the steps of:

(a) reacting at least one of a multifunctional isocyanate, a polyol and a chain extender, wherein at least two reagents selected from the isocyanate, the polyol, the chain extender, any mixture thereof and any pre-polymer formed therefrom, are intensively mixed to form a first polyurethane having a predetermined stoichiometry and thermal history;

(b) reacting at least one of a multifunctional isocyanate, a polyol and a chain extender, wherein at least two reagents selected from the isocyanate, the polyol, the chain extender, any mixture thereof and any pre-polymer formed therefrom, are intensively mixed to form a second polyurethane having a predetermined stoichiometry and thermal history which is different to the stoichiometry and thermal history of the first polyurethane; and

(c) injecting the first and second polyurethanes into a mould defining the polymeric product before the polymerization reactions associated with the production of the first and second polyurethanes are complete so that polymerization reactions between the first and second polyurethanes occur in the mould..

24. (Previously Presented) Apparatus for making a polymeric product having a gradual variation in modulus through at least a portion of the product comprising:

(a) a first delivery system for quantitatively dispensing at least two reagents selected from an isocyanate, a polyol, a chain extender, any mixture thereof and any pre-polymer formed

therefrom; the first delivery system including mixing means for intensively mixing said at least two reagents to form a first polyurethane having a predetermined stoichiometry,

(b) a second delivery system for quantitatively dispensing at least two reagents selected from an isocyanate, a polyol, a chain extender, any mixture thereof and any pre-polymer formed therefrom; the second delivery system including mixing means for intensively mixing said at least two reagents and reactive extrusion means to form a second polyurethane having a different predetermined stoichiometry to that of the first polyurethane, and

(c) means for injecting the first and second polyurethanes into a mould before polymerization reactions associated with the formation of the first and second polyurethanes are complete so that polymerization reactions between the first and second polyurethanes occur in the mould.

25. (Previously Presented) Apparatus for making a polymeric product having a gradual variation in modulus through at least a portion of the product comprising:

(a) a delivery system for quantitatively dispensing at least two reagents selected from an isocyanate, a polyol, a chain extender, any mixture thereof and any pre-polymer formed therefrom; the delivery system including first mixing means for intensively mixing said at least two reagents to form a first polyurethane having a predetermined stoichiometry,

(b) an intermediate vessel into which the first polyurethane is directed whilst the delivery system is used to quantitatively dispense at least two reagents selected from an isocyanate, a polyol, a chain extender, any mixture thereof and any pre-polymer formed therefrom; and second mixing means for intensively mixing said at least two reagents and reactive extrusion means to form a second polyurethane having a different predetermined stoichiometry to that of the first polyurethane, and

(c) means for injecting the first and second polyurethanes into a mould before polymerization reactions associated with the formation of the first and second polyurethanes are complete so that polymerization reactions between the first and second polyurethanes occur in the mould.

26. (Original) Apparatus according to claim 25, including a second intermediate vessel into which the second polyurethane is directed so that the first and second polyurethanes are injected from their respective vessels into the mould.

27. (Previously Presented) Apparatus according to claim 25, including a common injection port for injecting the first and second polyurethanes into the mould simultaneously.

28. (Original) Apparatus according to claim 27, comprising means for mixing the first and second polyurethanes prior to injection into the mould.

29. (Previously Presented) Apparatus according to claim 26, including means for varying one of the relative amounts of the first and second polyurethanes injected into the mould and the relative rates of injection of the first and second polyurethanes into the mould.

30-32. (Cancelled)

33. (New) An artificial spinal disc according to claim 18, further comprising a first end plate provided with the body and a second end plate provided with the body.

34. (New) An artificial spinal disc according to claim 33, wherein at least one of the end plates has a convex outer surface.

35. (New) An artificial spinal disc according to claim 33, wherein outer surfaces of at least one of the end plates define channels.

36. (New) An artificial spinal disc according to claim 33, wherein the first and second end plates are integral with the body.

37. (New) An artificial spinal disc according to claim 33, wherein there are no distinct interfaces between the first and second end plates and the body.

38. (New) An artificial spinal disc according to claim 33, wherein the first and second end plates are covalently bonded to the body.

39. (New) An artificial spinal disc according to claim 33, wherein at least one of the end plates is coated.

40. (New) An artificial spinal disc according to claim 33, wherein the first and second end plates comprise polymeric material.

41. (New) An artificial spinal disc according to claim 18, wherein the body comprises a nucleus region and an annulus region.

42. (New) An artificial spinal disc according to claim 41, wherein the body has an upper surface, a lower surface and a sidewall between the upper surface and the lower surface, wherein the annulus region separates the nucleus region from the upper surface, the lower surface, and the sidewall.

43. (New) An artificial spinal disc according to claim 41, wherein a Young's modulus of the nucleus region is less than a Young's modulus of the annulus region.

44. (New) An artificial spinal disc according to claim 43, wherein the pre-determined portion exhibiting the gradual variation in Young's modulus is between the nucleus region and the annulus region and the Young's modulus increases across the portion with increasing distance from the nucleus region.

45. (New) An artificial spinal disc according to claim 41, wherein the pre-determined portion exhibiting the gradual variation in Young's modulus is located within the annulus region and the Young's modulus increases across the portion with increasing distance from the nucleus region.

46. (New) An artificial spinal disc according to claim 41, wherein the Young's modulus is increased with increasing distance from the nucleus region in a radial direction.

47. (New) An artificial spinal disc according to claim 41, wherein the Young's modulus is increased with increasing distance from the nucleus region in an axial direction.

48. (New) An artificial spinal disc according to claim 41, wherein the Young's modulus within the nucleus region is substantially constant.

49. (New) An artificial spinal disc according to claim 18, wherein the variation in Young's modulus in the body is anisotropic.

50. (New) An artificial spinal disc according to claim 18, wherein the body comprises a polyurethane material.

51. (New) An artificial spinal disc according to claim 50, wherein the body comprises a first polyurethane material having a first stoichiometry and a second polyurethane material having a second stoichiometry.

52. (New) An artificial spinal disc according to claim 50, wherein the body comprises a nucleus region surrounded, at least in part, by an annulus region, the nucleus region comprising the first polyurethane material and the annulus region comprising the second polyurethane.

53. (New) An artificial spinal disc according claim 18, wherein the pre-determined portion exhibiting the gradual variation in Young's modulus comprises a polymeric material having a gradual variation in stoichiometry.

54. (New) An artificial spinal disc according to claim 18, wherein the variation in Young's modulus is continuous across the portion.

55. (New) An artificial spinal disc according to claim 18, wherein the spinal disc is a unitary component.

56. (New) An artificial spinal disc comprising:

a polymeric material structure including a nucleus region and a unitary annulus region, a Young's modulus within the nucleus region being less than a Young's modulus within the annulus region.

57. (New) An artificial spinal disc according to claim 56, further comprising a first end plate provided with the body and a second end plate provided with the body.

58. (New) An artificial spinal disc according to claim 57, wherein at least one of the end plates has a convex outer surface.

59. (New) An artificial spinal disc according to claim 57, wherein outer surfaces of at least one of the end plates define channels.

60. (New) An artificial spinal disc according to claim 57, wherein there are no distinct interfaces between the first and second end plates and the body.

61. (New) An artificial spinal disc according to claim 57, wherein the first and second end plates comprise polymeric material.

62. (New) An artificial spinal disc according to claim 56, wherein a pre-determined portion of the body has a gradual variation in Young's modulus.

63. (New) An artificial spinal disc according to claim 62, wherein the Young's modulus increases across the pre-determined portion with increasing distance from the nucleus region.

64. (New) An artificial spinal disc according to claim 62, wherein the pre-determined portion is located within the annulus region

65. (New) An artificial spinal disc according to claim 56, wherein the body comprises a first polyurethane material having a first stoichiometry and a second polyurethane material having a second stoichiometry.

66. (New) An artificial spinal disc according to claim 56, wherein the polymeric material structure is unitary.

67. (New) An artificial spinal disc according to claim 56, wherein the annulus region surrounds the nucleus region.

68. (New) An artificial spinal disc according to claim 62, wherein the pre-determined portion is located within the annulus region.

69. (New) An artificial spinal disc according to claim 56, wherein the body comprises a first polyurethane material having a first stoichiometry and a second polyurethane material having a second stoichiometry.

70. (New) An artificial spinal disc according to claim 56, wherein the polymeric material structure is unitary.

71. (New) An artificial spinal disc according to claim 56, wherein the annulus region surrounds the nucleus region.